SPECIAL CIVIL APPLICATION NO. 5700 OF 1983

Date of Decision: December 26, 1996.

For Approval and Signature :

The Honourable Mr. Justice S.D. Shah

1. Whether Reporters of Local Papers may be allowed to see the judgment? Yes

2. To be referred to the Reporter or not? Yes
Except [ ] portions

3. Whether Their Lordships wish to see the fair copy of judgment? Yes

4. Whether this case involved a substantial question of law as to the interpretation of the Constitution of India, 1950 or any order made thereunder? No

5. Whether it is to be circulated to the Civil Judge? No

Appearance :

Mr G.N. Desai & Mr P.G. Desai for petitioners

Mr K.C. Shah, learned AGP for respondents.

Coram : S.D. SHAH, J.
(Date: 26.12.1996)

CAV JUDGMENT :

1. Is human blood a "drug"?

AND

Are Pathologists tapping blood from human beings manufacturing "drug" so as to incur liability to obtain licence U/sec 18(c) of Drugs & Cosmetics Act, 1940?

are the questions posed for consideration of this court in this petition under Article 226 of the Constitution of India filed by some of the Pathologists and Association of Pathologists.

2. The respondents, namely, the Director of Food & Drugs has by notices, dated 8th July, 1983 called upon the petitioners individually to show cause as to why action should not be taken against them for breach of Section 18(c) of the said Act inasmuch as they have been carrying on the activities of tapping blood, collecting the blood and of selling the blood for which licence is required under section 18(c) of the said Act and since such activity was being carried on by them without obtaining licence, actions were required to be taken against them. The issuance of such notice to various pathologists has given rise to the present petition whereby the petitioners have challenged the legality and validity of said notices issued under section 18(c) and they have also prayed for issuance of appropriate writ, order or direction declaring that the pathologists are not liable to obtain any licence under the provisions of the said Act.

3. It is the case of the petitioners that the petitioner Nos 1 to 4 are registered medical practitioners possessing necessary medical degrees carrying on the noble profession as Pathologists in the city of Ahmedabad. It is their case that they only tap the blood from donor willing to donate his/her blood for a particular patient who may be in need of his/her (donor's) blood for treatment and who is referred to the pathologist by a medical practitioner. It is their further case that they do not stock the blood. They do not sell the blood nor do they distribute the blood to needy patients. It is their further case that the donor of the blood himself comes to the pathologists for tapping his blood for being given to the patient who is in need of blood and to whom the blood is offered by such donor at the recommendation of or at the instance of medical practitioner. It is their positive case that they do not sell the blood and by tapping the blood and making the same available to the relatives of the patient for being transfused they are simply discharging their professional services. The petitioners further contend that they have been carrying on such activities since long and therefore they were surprised when they received the impugned notice, dated 8.8.83 whereby the Director of Food & Drugs--the respondent No.1 herein has called upon them to obtain

licence under section 18(c) of the Drugs & Cosmetics Act, 1940. According to them human blood can not be regarded as "drug" and secondly pathologists can not be treated as "manufacturers of blood" so as to incur obligation to obtain licence under the provisions of the said Act. They have further submitted that all throughout the country nowhere such a demand is made by any authority acting under the provisions of the said Act, and therefore, also the respondents were not justified in calling upon the pathologists to obtain licence under the provisions of the said Act.

4. The Deputy Commissioner, Food & Drugs Control Administration, Gujarat State, has filed detailed affidavit-in-reply and has tried to justify the action of the Director of Food & Drugs Control Administration. It is the case of the respondents as can be gathered from the affifdavit-in-reply that the pathologists are collecting blood by a particular process which process and act of collection of blood would fall within the definition of "manufacturer" as defined by Section 3(f) of the Drugs & Cosmetics Act, 1940, hereinafter referred to as the "said Act". It is denied that the pathologists are collecting blood only from donors willing to donate his/her blood for a particular patient. For collecting blood the pathologists are supposed to carry out certain processes. Without which process the pathologists can not collect blood. It is because of particular process followed by the pathologists for collecting blood that they can be said to be manufacturing blood. According to respondents it is immaterial whether the pathologists charge their professional charges for rendering services of collecting blood. What is material is that while collecting blood they are undertaking certain processes because of which their activity would fall within the definition of "manufacture of drug" and therefore they are required to obtain licence under section 18(c) of the said Act. According to respondents, the pathologists are required to conduct certain tests for detecting V.D, Malaria, Jaundice, AIDS etc. They have further submitted that their aforesaid conclusion is supported by the fact that the Central Govt has inserted Part XII B in Schedule "F" to the Drugs & Cosmetics Rules, 1945. Said Part XII B is introduced in Schedule "F" of the said Rules vide notification, dated 7th July, 1967 and much reliance is placed upon the provisions of said Part XII B to which reference will be made hereafter in the course of this judgment. The respondents have very strongly relied upon this Part XII B introduced in Schedule "F" in the said Rules by pointing out that by said Part necessary conditions have been imposed for the "Blood Bank" which are required to be followed by the blood

bank. By necessary analogy they submitted that since the blood banks are required to obtain licence, the pathologists who are, by and large, carrying on similar activities are also required to obtain licence under section 18(c) of the said Act. They have also relied upon one additional fact, i.e. in the Indian Pharmacopoeia the standard of blood is prescribed and the "Whole Human Blood" is included in Indian Pharmacopoeia. As per Section 16(1)(a) of the Act and the Rule 124 of the Rules the standard of drug shall have to be maintained and it shall have to be as set out in Second Schedule of the said Act, and therefore, the blood which is to be collected by the pathologists should also conform to the said standard. Even for this purpose check on their activities is required and that check would only be achieved by subjecting them to the requirement of obtaining licence under the provisions of the said Act.

5. From the aforesaid narration of rival versions of the parties, this court is called upon to decide the first and primary question as to "Whether the human blood" can be said to be "drug"? To the common man the question may appear to be somewhat ludicrous. Very recently, an American Judge of the Supreme Court of America was faced with seemingly ridiculous question as to: Whether a Poney can be said to be a small bird and to the surprise of common man but to no surprise to the lawyers he held that Poney is a small bird. Looking to the need of Human Blood for treatment of variety of patients, by way of Blood Transfusion, legislative intention to include Human Blood in the definition of the term "drug" may not and for the reasons stated hereafter, shall not sound unreasonable or legislative will can not be said to have run riot.

RELEVANT STATUTORY PROVISIONS OF THE ACT:

6. Before this court proceeds to deal with the rival submissions made by the parties, it will be necessary to refer to some of the relevant provisions of Drugs & Cosmetics Act, 1940 which was enacted to regulate the import, manufacture, distribution and sale of drugs and cosmetics. Section 3 of the said Act enacts "definition clause" which defines various words and phrases used in the Act.

7. Section 3(b) defines "drug" as under:

"b" "drug" includes--
(i) all medicines for internal or external use of human beings or animals and all substances intended

to be used for or [in the diagnosis, treatment], mitigation or prevention of disease in human beings or animals; and

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the official gazette;"

8. Section 3(f) defines "Manufacture" as under:

(f) "manufacture" in relation to any drug [or cosmetic] includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug (or cosmetic) with a view to its sale and distribution but does not include the compounding or dispensing (of any drug, or the packing of any drug or cosmetic,) in the ordinary course of retail business; and "to manufacture" shall be construed accordingly;

9. Section 3(i) provides that the word "prescribed" would mean prescribed by the Rules made under this Act.

10. Chapter IV of the said Act is dealing with manufacture, sale and distribution of drugs. Section 16 deals with "standard quality" in relation to a drug. Section 17 and 17A deal with "misbranded drugs" and "misbranded cosmetics" respectively. Section 17B enacts a deeming provision as to when for the purpose of the said chapter a drug shall be deemed to be "adulterated drug". Section 18 deals with prohibition of manufacture and sale of certain drugs and cosmetics. If the State Government by notification in the Official Gazette imposes prohibition from such date, as may be fixed by it, no person shall himself or by anyother person on his behalf carry on the activities enumerated in the section. Since the Learned Counsel appearing for both the parties have placed much reliance upon the provisions of section 18, it would be just and proper to reproduce section 18 herein in its entirety:

"18. From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf no person shall himself or by anyother person on his behalf:--

(a) manufacture for sale, or sell, or stock or exhibit for sale, or stock or exhibit for sale, or distribute--

(i) any drug [or cosmetic] which is not of standard quality;

(ii) any misbranded drug or misbranded cosmetic;

(ii) any adulterated drug;

(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of ingredients contained in it in a manner readily intelligible to the members of the medical profession;

(iv) any drug which by means of any statement, design or device accompanying it or by anyother means, purports or claims [to prevent, or cure or mitigate] any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, or stock or exhibit for sale, or distribute any drug [or cosmetic] which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(c) manufacture for sale, or sell, or stock or exhibit for sale, or distribute any drug [or cosmetic], except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis;

Provided further that the [Central Government] may, after consultation with the Board by notification in the Official Gazette, permit subject to any conditions specified in the notification, the [manufacture for sale or for distribution, sale, stocking or offering for sale] or distribution of any drug or class of drugs not being of

standard quality"

11. From the aforesaid provision of section 18, and more particularly, clause (c) it becomes clear that the State Government is empowered to provide that no person shall manufacture for sale, or sell, or stock or exhibit for sale or distribute any drug except under, and in accordance with the conditions of, a licence issued for such purpose under this chapter.

12. Section 27 interalia provides that whoever himself or by anyother person on his behalf manufactures for sale, sells, stocks or exhibits for sale, or distributes any drug without a valid licence as required under clause (c) of section 18 shall be punishable with imprisonment for a term which shall not be less than one year, or which may extend to ten years and shall also be liable to fine.

13. It may be stated that under section 8 which finds its place under Chapter III captioned as "Import of Drugs", the expression "Standard quality" is defined to mean in relation to a drug, that the drug complies with the standard set out in the Second Schedule. Subsection (2) of section 8 empowers the Central Government to add to or otherwise amend the Second Schedule.

14. Section 16 which finds its place in Chapter IV captioned as "Manufacture, sale and distribution of drugs" also defines expression "standard quality" for the purpose of said chapter to mean in relation to a drug, that the drug complies with the standard set out in Second Schedule. Second Schedule to the said Act prescribes standards to be complied with by the drugs manufactured for sale, sold, stocked or exhibited for sale, sold, stocked or exhibited for sale or distributed. This court is not concerned with various other classes of drugs dealt with at item Nos 1 to 4A of the Schedule but item No.5 being relevant is reproduced herein:

"5. Other drugs:

(a) Drugs included in the Standards of identity
the Indian Pharmacopoeia. purity and strength spe-
cified in the edition of
Indian Pharmacopoeia for
the time being and such
standards as may be pre-
scribed.

(b) Drugs not included in the Standards of identity
Indian Pharmacopoeia, but purity and strength spe-

which are included in any cified for the Drugs in
Pharmacopoeia of any other the edition of such Phar-
country. macopoeia for the time
being and such standards
as may be prescribed."

15. From the aforesaid standard prescribed by the Second Schedule it becomes clear that all drugs included in the Indian Pharmacopoeia are included in the general category of "other drugs" and similarly all drugs not included in the Indian Pharmacopoeia but which are included in anyother Pharmacopoeia of another country are also included in the general category, namely, "other drugs".

16. Section 33 of the said Act empowers the Central Government to make Rules for the purpose of giving effect to the provisions of Chapter IV after consultation with the Drugs Technical Advisory Board constituted under section 5.

RELEVANT PROVISIONS OF THE RULES:

17 Having referred to the relevant provisions of the said Act it would now be necessary for this Court to make reference to the relevant provisions of Drugs and Cosmetic Rules, 1945, (hereinafter referred to as the said Rules).

18 Section 33(2) interalia provides that without prejudice to the generality of foregoing power, such rules may--

(a) provide for the establishment of laboratories for testing and analyzing drugs (or cosmetics)

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether a drug (or cosmetic) is of standard quality;

(d) prescribe, in respect of biological and organometallic compounds which a drug may bear or contain for purposes of coloring;

(e) prescribe the forms of licences for the manufacture for sale, for the sale and for the distribution of drugs or any specified drug or class of drugs [or of cosmetics or any specified cosmetic or class of cosmetics], the form of application for such licences, the conditions subject to

which such licences may be issued, the authority empowered to issue the same and the fees payable therefor;

(f) to (q) ... ..."

In exercise of powers conferred by section 6(2), 12 and 33 of the said Act, 1940, the Central Government has framed Rules known as "Drugs & Cosmetics Rules, 1945".

19. The Drugs & Cosmetics Rules, 1945, as amended, from time to time, assume importance in the context of the present controversy to the extent they provide for the licensing procedure. Rule 2 contains definition clause and clause (h) thereof defines "schedule" to mean schedule to the Rules. Part VII of the Rules is captioned as " Manufacture for sale [or for distribution] [of drugs other than Homeopathic Medicines]".

Rule 69 provides for application for grant or renewal of licence to manufacture, for sale, or for distribution of drugs other than those specified in Schedule "C" and C(1)

Rule 76 deals with forms of licence to manufacture drugs, specified in Schedule C & C(1) excluding those specified in the schedule. Such forms of licence are to be found in Form 28 & 28B. Form 28 is the proforma of licence to manufacture for sale (or for distribution of) drugs specified in schedules C & C(1) and X. Clause 3 of the said form is as under:

"3. The licence authorises the sale by way of wholesale dealing and storage or sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale."

[Rule 78 provides for conditions of licence in form 28 or 28B. It further provides that such licence shall be subject to special conditions, if any, set out in schedule "F" or "F(1)", as the case may be, which relate to the substances in respect of which the licence is granted. It thereafter prescribes the general condition which the licensee is required to comply with. Reference to various conditions prescribed by Rule 78 is not necessary at this stage, though it can be stated that the licensee is subjected to all reasonable conditions which are necessary to be imposed for the purpose of proper manufacture of drugs, maintenance of standards of drug, preservation, storage and stock of drugs and other precautions to be

taken by the licensee so that human health is not put to hazard.

Rule 79 provides for inspection by the Licensing authority before grant of licence. Such power includes power to examine plant and appliances, the process of manufacture intended to be employed and the means to be employed for standardising and testing the substances to be manufactured.

Rule 81 prescribes the procedure of licensing authority after it has made necessary enquiry and if the authority is satisfied that the requirement of the Rule under the Act have been complied with all the conditions of licence and the Rules under the Act will be observed, he shall issue a licence in form 28 or 28B.]

At this stage, it shall have to be stated that initially Chapter IV of the said Act was not brought into force along with the said Act but by subsequent notification issued by the then Government of Bombay, the Local Self-Government in Public Health Department, Sachivalaya bearing No.1056, dated 11th July, 1958. 1st August, 1958 was fixed as the date from which Chapter IV of the said Act came into effect in the whole of the State of Bombay. It is, thus, clear that section 18 of the said Act was brought into force with effect from 1st August, 1958 by the then State Government of Bombay. It is the case of the respondents that in view of the said notification the Pathologists who are collecting the blood are supposed to obtain licence under the said Act. It is also required to be noted that subsequently under the said Act by the Central Government in the Ministry of Health & Family Welfare Department Notification No. SO-2369, dated 7.7.69 Part XII B in Schedule F in the said Rules was inserted. By the said insertion of Part XII B Schedule F necessary conditions have been imposed for the Blood Bank. Since the respondents rely upon this Part XII B Schedule F and since it is the case of the petitioners that said Part XII B Schedule F would not apply to any person other than the Blood Bank it would be necessary at this stage to make reference to said notification of the Central Government dated 7.7.67 whereby Part XII B came to be introduced in Schedule F of the schedule. Schedule F to the said Rules is divided into Part I to Part XIIA and XII B. Part XII B deals with equipment and supplies required for a blood bank. It then proceeds to prescribe the requirement of an ideal Blood Donor Room. Said room shall be an air-conditioned room. It then prescribes blood collection supplies by providing that it shall be done either by the

closed method or by the gravity method. It also provides for Haemoglobin determination, temperature and pulse determination, canteen equipment, emergency equipment. It also prescribes the requirements of laboratory, such as equipments, regents, General supplies, Technical Staff, Accommodation for Blood Bank, Label for whole blood, Colour scheme for Labels etc. It then contains precautionary measures to be observed by the Blood Bank which interalia, include:

1. Administer without warming.
2. Shake gently before using.
3. Do not add other medication to the blood.
4. Check blood group on label and recipient's group before administration.
5. Use a fresh, clean, and sterile transfusion set to transfuse the blood.
6. Do not dispense without prescription.

Below this prescription of conditions to be observed by " blood bank and laboratory" there is one note prescribed which reads as under:

> "Note: The above requirements of the blood bank are subject to modifications at the discretion of the Licensing authority if he is of the opinion that having regard to the extent of manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case"

20. Incidentally, it may be stated that the Drugs & Cosmetics (1st Amendment Rules), 1993 are framed by the Central Government after consultation with the Drugs Technical Advisory Board in exercise of powers conferred by Sections 12 and 33 of the Drugs & Cosmetics Act, 1942. It appears that prior thereto after Part X of Schedule X, Part X-A came to be introduced and by the aforesaid Amendment Rules, 1993 published in the Govt.Gazette of India on 22.1.1993 Part XB is inserted. The heading of Part XB is as under:

"REQUIREMENT FOR THE COLLECTION, STORAGE, PROCESSING AND DISTRIBUTION OF WHOLE HUMAN BLOOD, HUMAN BLOOD COMPONENTS BY BLOOD BANKS AND MANUFACTURE OF BLOOD PRODUCTS"

> "122-F: Form of application for licence for operation of Blood Bank/Processing of whole human blood for components/manufacture of Blood Products

for sale or distribution--(1) Application for the grant and/or renewal of licence for the operation of a Blood Bank/Processing of Human Blood for components/manufacture of Blood Products shall be made to the licensing authority appointed under Part VII in Form 27-C and shall be accompanied by licence fee of rupees six hundred and inspection fee of rupees two hundred in the case of renewal licence;

Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry the fee payable for the renewal of the licence shall be rupees six hundred plus an additional fee at the rate of rupees two hundred per month or a part thereof in addition to the inspection fee.

Provided further that a licensee holding a licence in Form 28-C for operation of blood bank/processing of whole human blood for components/manufacture of blood products shall apply for grant of licence under sub-rule (1) before the expiry of the said licence on Form 27-C and he shall continue to separate the same till the orders on his application are communicated to him.

Explanation: For the purpose of this rule a blood bank means a centre for collection, storage, processing and distribution of Whole Human Blood and/or Human Blood Components from selected human donors"

(2) A fee of rupees one hundred shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

(3) Application by a licensee to manufacture additional drugs listed in the application shall be accompanied by fee of rupees fifty for each drug listed in the application.

(4) On receipt of the application for the grant or renewal of such licence, the licensing authority shall:--

(i) Verify the statements made in the application form;

(ii) cause the manufacturing or testing establishment to be inspected in accordance with the provision of Rule `122-I, and

(5) If the licensing authority is satisfied that the applicant is in a position to fulfil the requirements laid down in the rules, he shall prepare a report to that effect and forward along with the application to the Central Licence Approving Authority;

Provided that if the licensing authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules, he may by order for reasons to be recorded in writing, refuse to grant or renew the licence, as the case may be.

(6) If, on receipt of the application and the report of the licensing authority referred to Sub-rule (2) and after taking such measures including iunspection of the premises by the Inspector, appointed by the Central Government under section 21 of the Act and/or along with the expert in the concerned field if deemed necessary the Central Licence Approving Authority is of the opinion that the applicant is not in a position to fulfil the requirements laid down in these rules he may, notwithstanding the report of the licensing authority by order, for reasons to be recorded in writing, reject the application for grant of renewal of licence as the case may be and shall supply the applicant with a copy fo the inspection report"

By introduction of said Part, Rules 122 F to 122 P are introduced and stricter provisions are made for making application for licence for operation of Blood Bank/Processing of whole human blood for components/manufacture of Blood Products for sale or distribution. The requirement of licence allegedly confined to Blood Banks only is now made applicable for the operation of Blood Bank/Processing of whole human blood for components/manufacture of Blood Products and these

Amendment Rules of 1993 thus include within its sweep those who are processing whole human blood and the components or those who carry on activity of manufacture of blood products. Even Part XII B of Schedule F of the said Rules is substituted and stricter conditions are prescribed. The rigorous standards introduced by the Rules to prevent the spread of HIV (which can cause AIDS) and other disease causing viruses. These disease preventing measures needed to be nonnegotiable. Instead the rules confer discretion on the licensing authority or central license approving authority having regard to the extent of the manufacturing operations, to relax or alter the requirements in the circumstances of a particular case.

21. At this stage it would be appropriate to refer to item No.5 (already set out hereinabove) of the 2nd schedule to the said Act. The said item is residuary item and deals with other drugs. It prescribes the standards of identity, purity and strength for drugs included in the Indian Pharmacopoeia, and it also prescribes standards of identity, purity and strength of drugs not included in the Indian Pharmacopoeia but in any other pharmacopoeia of another country. In this connection it will be appropriate at this stage ton refer to "Pharmacopoeia of India", Volume I, 3rd Edition published by the Government of India, Ministry of Family Health Planning. In the 3rd Edition of said book "Whole Human Blood" is described and its standards for drawing the same from selected human donors are also prescribed. The process of drawing the blood, putting it in proper container, grouping it, storing it and labelling it is also prescribed. It would be appropriate to set out in its entirety the description of "Whole Human Blood" given in Pharmacopoeia of India as it would help the court in deciding as to whether "Blood" is "drug" or not.

> "Deep-red fluid which, on standing, separates into a lower layer of sedimented red cells and a yellow, almost clear, upper layer of plasma, free from visible signs of haemolysis, with a greyish layer between the two consisting of leukocytes and thrombocytes. A layer containing emulsified fat may form on the surface."

COURT'S CONCLUSIONS ON QUESTION NO.1

IS HUMAN BLOOD 'DRUG' WITHIN THE MEANING OF SECTION 3(b) OF THE ACT?

22. Having seen the relevant provisions of the Act and the Rules as amended from time to time it would be necessary for this court firstly to ascertain as to whether Blood or whole human Blood is a "drug" as defined by section 3(b) of the said Act. From the definition which is reproduced hereinabove it becomes clear that all substances intended to be used for or in the diagnosis, treatment, medication or prevention of any disease or disorder in human being can be said to be "drug". The court is first called upon to decide as to whether the "blood" is "drug" or not? Mr.K.C.Shah, Ld.AGP appears to be right in contending that the entire petition proceeds on the assumption that the "blood" is "drug" and that no challenge, whatsoever, is made in the petition to the effect that the blood is not drug. In my opinion, inclusive definition of "drug" would include "blood" as it is undoubtedly a substance which can be used for or in the diagnosis, treatment, prevention of any disease or disorder in human being. Transfusion of matching human blood of the same group is now a well-known treatment adopted by the medical profession for treatment, medication or prevention of any disease or disorder in human being. The concept of total blood transfusion by transfusing matching blood of same group of another person in case of patient suffering from blood cancer in its primary stage is also a well-known process. Therefore, there is no manner of doubt that the blood is "drug" within the meaning of section 3(b) of the said Act.

23. Firstly, the fact that the schedule 2 contains item No.5 and prescribes the standards of identity, purity and strength of drugs included in Indian Pharmacopoeia coupled with the fact that Indian Pharmacopoeia contains the Whole Human Blood as "drug" is material. Secondly, the standards prescribed for Whole Human Blood i.e. blood drawn from selected human donors and mixed with suitable anticoagulant would leave no room for doubt that the legislature while enacting the Act and more particularly while prescribing the drugs for which standards are to be laid down, intended "human blood" to be included as a drug and therefore it has very meticulously prescribed the standards both for the donor as well as the person who is drawing the blood and is either collecting the same, storing the same, giving the same for transfusion or distributing the same for transfusion. Thirdly, the process of drawing itself is very elaborate process and number of prescriptions enacted are to be followed. It is not that as soon as the blood is collected or drawn from selected donor the same is given over to the relative of the donor who has to use it for the patient. Irrespective of the selected human donor who is

allegedly brought to the pathologists by the relative of patient, as suggested by the petitioners, any person drawing the human blood is required to follow the standards prescribed and the standards are elaborate and full of precautions and unless there is proper check and supervision, mere drawing of blood from the body of a selected human donor may also include spread of number of diseases. Fourthly, the legislature in fact wanted that human blood of the standards prescribed by Indian Pharmacopoeia is available and that too from the permissible sources only. Drawing or distribution of human blood by persons who are not subjected to supervision or overall control of independent body may give rise to blood of inferior quality or sub-standard blood of donor suffering from various diseases, such as, Viral Hepatitis, infectious diseases, malarial fever, Syphilitic infection, or persons having positive evidence of AIDS being supplied or distributed or sold as human blood, ultimately to be transfused to innocent patients, who might also develop such disease which the blood of the donor contains and therefore the legislature undoubtedly has prescribed the standards which are to be fulfilled by everyone who indulges into any activity of drawing blood, collecting the same in container, mixing the same with suitable anticoagulant, storing the same for appropriate time and giving the same to any person for the purpose of being transfused. Keeping all these factors in mind, it is difficult to accept that human blood is not "drug" within the meaning of said term as defined by Section 3(b) of the said Act, more particularly,in light of item No.5 and the definition of "Whole Human Blood" given in Pharmacopoeia of India. It would also amount to permitting every individual to deal in human blood irrespective of any regulation or control which ultimately would lead to spread of number of diseases which are generated by transfusion of sub-standard Blood-"Drug". Lethargy in not closely examining the donor of the blood and tendency to make easy money by drawing blood from all persons who are living below the poverty line, by selling their human blood in exchange of money which may hardly provide bare sustenance for a day or two, to earn their bread thereby, is required to be discouraged, depricated and condemned in a country like India. It is trite knowledge that blood for transfusion is not only available from Blood Banks, but almost in all metropolis there are large number of professional donors who offer themselves for drawing blood, who charge or who are paid the amount by the doctors or pathologists. Such blood is thereafter sold or distributed to persons who are in need of it as "drug" since it is required to be transfused at the time of operation, blood transfusion or to deal with number of other diseases as treatment. If such activity is

permitted without any regulation or control the Indian society would be put to great health hazard and therefore with a view to giving full scope to the legislative intention it would be just and proper to hold that human blood is "drug".

CONCLUSIONS ON QUESTION NO.2

WOULD THE ACTIVITIES CARRIED ON BY THE PETITIONERS-PATHOLOGISTS FALL WITHIN THE DEFINITION OF 'MANUFACTURE' AS DEFINED IN SECTION 3(f) SO AS TO ATTRACT "LICENCE" PROVISIONS?

24. The question squarely arises for consideration because of provisions of Section 18(c) of the said Act which is extensively reproduced hereinabove. Section 18 finds its place in Chapter IV which deals with manufacture, sale and distribution of drugs. Section 18 is captioned as "Prohibition of manufacture and sale of certain drugs and cosmetics." Section 18 interalia provides that from such date as may be fixed by the State Government by notification in the official gazette in this behalf, no person shall himself or by any other person on his behalf manufacture for sale or sell or stock or exhibit for sale or distribute any drug which is not of standard quality. Subclause (c) of section 18 further enacts that from the date fixed by the State Government by notification no person shall manufacture for sale or sell or stock or exhibit for sale or distribute any drug except under and in accordance with the conditions of licence issued for such purposes under this chapter. It is thus clear that by issuing a notification in the official gazette the State Government may fix the date from which no person shall be in a position to manufacture for sale or sell or stock or exhibit for sell or distribute any drug unless the licence is issued for such purpose. As noted hereinabove, section 27 of the Act prescribes penalty for manufacture, for sale, for selling, stocking, exhibiting for sale or distribute any drug without a valid licence as required under clause (c) of section 18.

26. Blood is an essential component of body which provides sustenance to life. There can be no greater service to the humanity than to offer one's blood to save the life of other fellow human-beings. At the same time, blood, instead of saving life, can also lead to death of the person to whom the blood is given if the blood is contaminated. As a result of developments in medical science, it is possible to preserve and store blood after

it has been collected so that it can be available in case of need. There are blood banks which undertake the task of collecting, testing and storing the whole blood and its components and make the same available when needed. In view of dangers inherent in supply of contaminated blood, it must be ensured that the blood that is available with the blood banks for use is healthy and free from infection. At the same time, it shall have to be kept in mind that the story of blood donors straight way going to pathologist or pathological laboratory for donating their blood for being given to the relative is not worth of acceptance. In fact, the notices issued to the petitioners clearly state that there is primafacie case with them to hold that the petitioners are selling blood after obtaining the same from professional blood donors. It is now found that no medical check up is done of the blood sellers, their health status is not examined. The blood trade flourishes with poor people like unemployed, rickshaw pullers, drug addicts selling the blood. Such blood sellers suffer from various infections and their haemoglobin is lower than the prescribed level. It has been reported that there are many persons who donate blood 5 to 6 times in a month; poverty makes them to do so at first but later it is reported to become like an addiction, the blood seller enjoying the dizziness due to reduced supply. In some places, strong middle men operate for the blood banks by arranging for donors. The middle men dictate the charges to be paid and take a heavy commission; the selection of donors disregards the level of health etc. A large part of the professional donors are alcoholics or drug abusers, have indiscriminate sexual habits and are a high risk group for Hepatitis B and AIDS and are unfit to donate blood.

27. In the light of the aforesaid actual fact situation prevalent, it is unsafe to rely upon the tall claim of the petitioners that they are rendering professional services for which they charge professional fee and that they can not therefore be subjected to regular licensing process.

Hundreds of thousands of young people living in small towns or villages, in an inner revolt to break loose from it, get to the cosmopolitan cities or industrial townships.

It is seldom that these people get employment of their choice or suitability. Once their money is exhausted, it becomes difficult for them to persist without food for long.

It is the agents who are alert in these areas who get to book these people by playing on their sentiments. It is suggested to these simple folks by the agents that either a small child or a pregnant woman is on death bed and if he could give a little amount of blood to save the patient, he can get some money as reward. The agents make it convenient to suggest that such a deed may fetch him luck to get him into suitable employment. In the meantime he can come out of the immediate crisis, further argues the tout. It is rarely that the agent fails with such a tactical motivation. They escort such persons at od times and get them to be bled, when the other donors are preferably not around, the new donor is bled for two bottles at a time and payment is made for a single unit; or payment is given less than the announced amount.

Unfortunately, with the cash of Rs.80.00 (which is the prevailing rate) he can barely keep himself afloat for more than a few days. He is again pennile. Sooner or later he returns to the blood bank to try his luck again. It is now that he learns of the timings and of the procedures. If he is lucky to be in time, he is bled or else he has to return back later. For as many as 3 to 4 times in the beginning he gets qualified continuously after which he is rejected to join the group of chronic professional blood donors.

Thus, coming in contact with professionals blood donors he is perplexed when he learns that people have been at it for 10 to 38 years and are living by these means. Some are married and care for their families with this money. The fear of giving blood disappears and he treads slowly into the profession with the absorbed knowledge of self medication and the spirit of excitement.

The commercial blood (banks) or suppliers today control more than 80% of the blood and blood product requirements of the country. The blood is sold by them as essential life saving drug and therefore its price has not been allowed to be controlled.

Professional Blood Donors--Who encourage them?

The Commercial Blood Banks or Suppliers are a big racket and it (racket) exists because the medical profession is totally indifferent about the quality of blood being transfused. Who is patronising the commercial blood banks? Doctors are still directing patients to these blood banks. If only doctors could take a stand on this, commercial blood banks would close down.

Many State Government Blood banks in Delhi depend on outside sources (commercial) as their in-house-banks do not collect enough due to noninsistence on relatives to donate. For example, Safdarjung Hospital has a total requirement of 17,500 units per year; replacement donors number 4250; from Indian Red Cross Society 2,250 units are obtained and from commercial sources 11,000 units are needed every year.

Is it not true that the State is aiding and abeting Professional Blood Donation? Voluntary movement could catch on as it did in Chandigarh which collects all the blood it needs from voluntary blood donations.

Another factor responsible for encouraging commercial blood donors is the mushrooming of private hospitals/nursing homes all over the country. Hospitals like Jaslok and Beach Candy in Bombay depend mostly on blood supplied by Commercial Blood Donors.

SUBMISSIONS:

28. Mr.G.N.Desai, Learned counsel appearing for petitioners has very vehemently submitted before this court that the activity of drawing blood or tapping blood for the purpose of matching the blood of donor with that of the patient and the activity of supplying such blood to patient or relatives of the patient or donor would not fall within the definition of term "manufacture" as defined by section 3(f) of the said Act. By reference to the definition of "manufacture" which is extensively quoted hereinabove he very vehemently submitted that even if blood is assumed to be "drug" the activities of the pathologists so as to fall within the definition of "manufacture" must amount to any process or part of process for making, altering, ornamenting, finishing, taking, labeling or otherwise drawing or tapping with a view to sell or distribute. In his submission, the process of tapping the blood or drawing the blood, testing the blood and cross-matching the same with that of the patient, collecting the same in a container and supplying the same to the donor and/or relatives of the patient by taking proper care would not amount to manufacturing any "drug", and therefore, the pathologists can not be subjected to licensing process of section 18(c) of the said Act. He, very forcefully, submitted that the aforesaid professional activities

conducted by the pathologists would not amount to process of making, altering, ornamenting or labeling the blood. In the alternative, he submitted that even if it is assumed that the process carried on by the pathologists would fall within the definition of "manufacture" every manufacturing activity does not require licence. If the definition of "manufacture" is read with section 18(c) the licence is required for manufacture of blood provided such manufacture is for sale or sell or stock, for exhibiting for sale or distributing the blood. He submitted that the pathologists neither sell nor stock nor exhibit for sale nor distribute blood and therefore section 18(c) does not require the pathologists to obtain a licence. It is their further assertion unsupported by any material, that no payment is made by them to the donors of the blood. It is admitted by them that they charge their professional fee from the relatives of the patients or the donor for drawing the blood, for matching the sample and for certifying that the blood of the donor was matching with that of the patient and for collecting the same and supplying the same in the container to the patient and/or their relatives. It is further assertion that, once again unsupported by any material, that they do not maintain either register or list of donors or their addresses nor do they stock the blood for commercial distribution. Based on said assertion, their further case is that for professional services rendered by them for which they charge professional fee they cannot be subjected to regular licencing process enacted by Section 18(c) of the said Act, which only applies only to "Blood Bank."

Secondly, Mr.Desai submitted that when there is no notification issued by the State Government in the official gazette as required by section 18 prohibiting manufacture, sale etc. of blood without licence, said section can not be used for regulating otherwise professional activity of pathologists. He submitted that the respondents were not justified in referring to and relying upon Part XII B of Schedule F to the Drug and Cosmetic Rules as the said notification is issued by the Ministry of Health & Family Planning (Department of Health), New Delhi on 7th July, 1967 whereby the Drugs and Cosmetic Rules, 1945 are further amended and Part XII B is introduced. If said Part XII B is closely read it prescribes various standards to be followed by the Blood Bank and by laboratory. He placed much reliance upon the foot note to the said notification which is already set out hereinabove and which provides that the above requirements of Blood Bank are subject to modification at the discretion of the Licensing Authority. In his submission, therefore, Part XII B which came to be

inserted in Schedule F of the said Rules, 1945 is simply applicable to a Blood Bank and not to pathologists or laboratories of pathologists and therefore the said notification can not be pressed into service. In fact, the petitioner Nos 1 to 4 who are pathologists running various laboratories have received identical notice, dated 8th July, 1983 from the Director, Food and Drugs--the respondent No.1 to the petition whereby it was asserted that the Drug Inspector from the office of the respondent No.1 has visited the laboratory of the concerned pathologists in the month of January, 1983 and has after inspection noticed that each petitioner No.1 to 4 is ordinarily drawing and collecting the blood from commercial donor and that the same was being sold to the needy patients at the price of Rs.120. It may be stated that as on date the bottle of blood is being sold at a price of more than rupees 800/-. It is further stated in the notice that even the definition of "drug" the blood is a drug and for that purpose of tapping or drawing blood, for collecting the same and for selling the same a licence is required. While each pathologist was carrying on the said activity without obtaining licence and thereby he has committed breach of section 18(c) of the said Act. By the same notices, which are annexed at annexure "A" to the petition and which are verbatim the same, the petitioners Nos 1 to 4 are further directed not to tape, draw the blood from any donor and not to sell the same unless licence in that behalf is obtained under section 18(c) of the said Act. It is further stated that despite such notices issued to petitioner No 1 to 4 N.H.Bhatt,J while admitting the petition at the stage of issuance of notice fully granted ad-interim relief restraining respondent No.1 from acting upon or implementing or proceeding further with the notice issued to pathologists, and such order of injunction has unfortunately operated for over a period of more than 11 years and the pathologists have continued their "professional activity". It is, therefore, submitted that this petition, in any case, shall have to be allowed partially, even if the court takes another view, by qusshing and setting aside the impugned notices, as they do not provide any fresh foundation for instituting action against the petitioners for launching criminal prosecution against them and no useful purpose will be served by permitting the respondents to act upon such stale notices allegedly based on stale material, and therefore, the petition should not be dismissed as premature as it has successfully achieved the objective of thwarting the State action by ad-interim injunction which was granted by the learned single judge. The State having not taken any action to get vacated or modified such ad-interim injunction for a period of more than 12 years can not now

succeed and the respondents can not be permitted to proceed further on the basis of such stale notices and stale material allegedly collected. Part of the petition is, therefore, in any case, required to be allowed. It can not now be rejected as premature because it has lived its utility and it is not proved to be a stale writ or fruitless writ. If the State was inactive it must atleast suffer the consequences of its inaction and omission and the impugned notices in question are therefore required to be quashed and set aside even if the court holds that the activities of the pathologists fall within the ambit of the word "Manufacture".

DEFENCE OF THE RESPONDENTS:

29. The stand taken by the respondents and, more particularly, by the Director, Food & Drugs, is to be found in the affidavit-in-sur-rejoinder filed by A.I.Shah, Deputy Commissioner, Food & Drugs Control Administration, Gujarat State. It is firstly contended by Mr.K.C.Shah, Ld.Asst.Govt.Pleader, based on the said affidavit that the petition is premature and is filed at the stage of issuance of show cause notice only and without even replying to the show cause notice and hence the petition is liable to be dismissed. Secondly, it is submitted that petitioner Nos 1 to 4 who are Pathologists running Pathology Laboratories were in fact collecting blood and selling the same and therefore notices under challenge were issued to them to obtain necessary Drug Licences under section 18(C) of Drugs & Cosmetics Act, 1940. If reference is made to such notices they called upon the petitioners to tender their explanation within 7 days from the receipt of notice, dated 8th July, 1983 and without tendering any explanation the petitioners have rushed to the court and therefore the petition at this stage should not be entertained. Thirdly, it is submitted by them that the petitioners are in fact tapping and/or collecting the blood from professional donors and/or storing/stocking the same as per the matching group and they are selling the same or offering for sale to the needy patients or relatives of the patients for the purpose of using the same for treating the ailment of mitigating or preventing any disease. The word "drug" is widely defined and the definition which includes all substances intended to be used for or in the diagnosis, treatment, medication or prevention of any disease or disorder in human being. It is their further case that even if reference is made to the 2nd schedule to the said Rules, as far as "other drugs" are concerned all other

drugs which are included in Indian Pharmacopoeia are to be treated as drugs. Since whole human blood is undoubtedly "drug" and various processes carried on by Pathologists, such as, drawing or tapping the blood from donor, collecting the same, group matching or cross-matching the same, labelling the same and supplying the same for consideration would amount to manufacturing activity and therefore even the Pathologists who run regularly laboratory and are carrying on aforesaid process are required to possess licence under section 18(C) of the said Act. Fourthly, reliance is placed upon the fact that a clear allegation is made in the notices issued against the petitioners that they are in fact collecting/tapping blood from professional donors and/are selling the same and such allegation is not replied to. It is further submitted that even for the purpose of taping/collecting the blood, storing the same certain process is required to be followed. If one refers to the standards prescribed for "whole human blood" in Indian Pharmacopoeia and therefore even for such activity admittedly carried on by the petitioners they were required to obtain licence under section 18(C) of the said Act. It is further pointed out that by Notification of the Central Government dated 7.7.67 Part XII B is introduced in Schedule F of the said Rules by which necessary conditions have been imposed for the Blood Bank and Laboratories and since Pathologists who are running Laboratories are carrying on the manufacturing activity, they are also required to observe the conditions laid down by the said Part XII B. It is their further case that various tests prescribed at the time of collecting or tapping the blood and various precautions which are required to be observed are with a view to detecting the presence of bacteria or genes of certain fatal diseases, such as, AIDS, VD, Jaundice or Hepatitis or Malaria. If the pathologists are not subjected to licence required they would carry on activities of tapping/collecting the blood from the professional donors without scrupulously following the standards prescribed which ultimately result into spread of diseases like AIDS, VD, Malaria, Hepatitis etc. This would result into spread of such diseases to the person to whom such blood is transfused and it was pointed out that in the State of Gujarat also in past diseases of Jaundice or Hepatitis spread like an epidemic because of failure of certain pathologists in autoclaving syringes for injunction and because of transfusion of blood of persons under the influence of Jaundice and/or Hepatitis. It is, therefore, submitted that if the pathologists are subjected to certain regulatory restrictions by insisting that they should obtain licence for their systematic activity of collecting/tapping blood from professional donors, storing the same and selling the same can be very well looked into

and spread of diseases can be largely curtailed or totally prevented. The activities which are prescribed by section 18(C) are not only confined to selling of blood but the same are applicable to even collecting/tapping the blood, storing/stocking the blood, selling the blood or exhibiting the same for sale or even distributing the blood. Distribution of such blood allegedly tapped from voluntary donors would also fall within prescribed activity and it would not be simply professional service rendered by pathologists as alleged by the petitioners. By elaborate reference to the standards prescribed for Whole Human Blood in Indian Pharmacopoeia it is submitted before the court that the standard of identity, purity and strength specified in the Indian Pharmacopoeia are required to be observed and various other standards for storing, labelling etc. are also required to be observed. It is an admitted fact that when the Whole Human Blood is drawn from selected human donors for its maintenance with suitable anticoagulant certain other conditions are prescribed. Reference to such conditions also assumes importance and in this connection they have referred to the conditions prescribed by Indian Pharmacopoeia. Age group of the donor of the blood, content of Haemoglobin, his medical history, requirement of his not suffering from any infectious skin diseases, requirement of his not having any history of viral hepatitis or close contact with an individual having viral hepatitis etc. assume great importance and the further requirement that the donor should be free from HIV antibodies is also an important requirement. Whether human blood donated by the donor is free from HIV antibodies is to be tested from such laboratories as may be specified for the purpose by the Central Government and the date of performance of such test is also required to be recorded on the label of the container. It is submitted by the respondents that the activities being carried on by the petitioners are to be read in the context and if the standards are not insisted to be carried by the pathologists, spread of serious diseases like AIDS, Hepatitis-B, Malaria etc. would be beyond control and a time would come when there would be a large number of persons suffering from serious diseases like AIDS etc. It is pointed out by them that in the information supplied by the Deputy Director of Health Services (Academic), Gandhinagar for the period between 9/86 to 8/91, 68723 blood samples were screened for HIV test out of which 689 samples were found to be of LISA positive and 182 samples were found to be WB positive. As per the recent report from one hospital, i.e.Vadilal Sarabhai Vadilal Hospital published in the month of 9/95 it has detected 104 HIV cases. The Municipal Health Committee Chairman has categorically stated that almost all cases are the results

of blood transmissions and not by sexual transmission. Similarly, at Shardabai Sarabhai Chimanlal Municipal Hospital 15/20 HIV positive cases are admitted. The report further finds that in Ahmedabad alone the figure crosses 1200 (vide report published in the Times of India, dated 7/9/95). It is submitted that after the said blood is given to the patient without testing and if it is found virus of HIV + it is likely that the disease of AIDS might spread which can not be cured. At this stage, if reference is made to recent study of blood samples in the State of Gujarat, it would be clear that the deadly disease of AIDS is very fast spreading in the State of Gujarat which would create greatest health hazard not only in Gujarat but in the adjoining States as well as in the country. Since the virus enters the body through blood transfusion among other modes, testing of every blood sample is the best preventive step. AIDS--Acquired Immune Deficiency Syndrome is caused by virus which go under the name of Human Immunodeficiency Virus-HIV. The person with HIV virus in his blood take years for the infection to surface, after lying dormant in the intervening period. All the same they are infectious. At some point, the immune system becomes so weak that one or several diseases may afflict the person. He dies eventually of general weakness and delibility or through diseases including cancer. There is no vaccine as yet invented as a panacea. The present state is that all those who become infected by the virus, by whatever means, will eventually come down with the syndrome and after much suffering, they will die. The choice before the Government is limited in view of the fact that no cure is as yet available. The only choice is to halt and, if possible, reverse the spread. All blood samples must be necessarily screened if this is to be achieved. Since AIDS cases are already reported in Gujarat, and looking to the explosive rate of its spread in many countries, it is high time that strict all round enforcement steps were immediately taken, to prevent AIDS becoming pandemic in Gujarat. Prevention is better than cure, and where is no cure, prevention is the only answer. It is, therefore, necessary that the pathologists should obtain licence under the said Act, and Rules made thereunder in the larger interest of health of people.

30. In order to buttress the submission that the activities carried on by petitioners are in fact manufacturing activity, Mr.K.C.Shah, Ld.AGP has placed reliance on some of the observations made by well-known author Kania L.Mukherjee in Vol.I of "Medical Laboratory Technology".

(i) In chapter 15 of the said volume captioned as "Principles of Immunohematology and Clinical Significance of Blood Transfusion" two authors have categorically observed as as under:

> "Blood is essential for human life. The blood volume of normal adults in a developing country is approximately 4 litres. The cellular phase (approximately 45%) of whole blood consists of red cells, white cells and platelets, which perform the vital functions of oxygen transport, defence of the body through immunologic reactions and stoppage of bleeding respectively. The non-cellular liquid phase (approximately 55%) is called plasma, which contains various chemicals, antibodies, and coagulation factors. The cellular components can only function when they are able to float in the plasma and move freely through the network of the body's circulatory system. In many diseases and health problems, therapeutic administration of blood is indicated. The technique of replacing blood and its components is called blood transfusion.
>
> Blood transfusion is a major medical service which is provided through blood banks. The functions of blood bank include collection of blood from healthy donors, storing it, processing it and supplying it to the needy recipients. The blood banks perform a number of tests for the safety of the recipient. The chosen donor's blood for the recipient should be compatible with recipient's blood and free from transmissible diseases. It is a responsible job and must be done accurately. In case of incompatible transfusion, serious complications may develop in the recipient (the patient) which may lead to his death following haemolytic transfusion reaction"

(ii) From the aforesaid observations he has stressed that the blood transfusion is a medical service which is provided through Blood Banks and their functions include collection of blood from healthy donors, storing it, processing it and supplying it to the needy recipients. The blood bank performs number of tests for the safety of

the recipients. When these very functions or some of the functions of the blood bank are conducted or undertaken by institution other than the Blood Bank or Pathological Laboratories and admittedly when such blood is transfused as a treatment to a recipient of blood, the pathologists or pathological laboratories are required to perform number of tests for the safety of recipients. It is undoubtedly a responsible job and must be done accurately.

> "Blood transfusion today is a major medical service that is rendered to patients needing replacement of whole blood components. Major developments in the field of blood transfusion have occurred since the beginning of the second world war. During this period, transfusion of blood and blood products has become accepted as a routine and relatively safe procedure in the management of patients. The blood bank tries to select a donor's blood that will be compatible with recipient's blood. The recipient's plasma should not have any reactive antibody towards the red cell of donor which may lead to haemagglutination or haemolysis of donor's red cells".

In Chapter 16 of the very volume captioned as "Collection and Processing of Blood for Transfusion" the authors have observed as under:

> "Blood must be collected from a healthy donor using aseptic technique, carefully transported to the blood bank laboratory, and properly stored until transfused into the patient (recipient) within the prescribed period of storage. Contaminated blood will produce adverse reactions in the recipient following transfusion therapy. The collected blood is later processed in the laboratory to obtain its components for specific therapy. Before the blood is collected from the donor, the container for blood collection must be carefully prepared. It must have appropriate anticoagulant of suitable quantity and must be hermetically sealed to avoid bacterial contamination or introduction and formation of pyrogen"

In this chapter number of safeguards are enumerated

starting from preparation of blood collection bottles, their sterilization with anticoagulant, metal cap, how the bottle should be closed, how they should be cleaned, how the pilot tubed should be attached to the bottle, how anticoagulant solution should be prepared etc. In that chapter under the caption "blood collection" the authors have observed as under:

"Collection of whole blood is one of the most important functions of the blood bank. Good health of the donor should be carefully checked out before collecting the blood which is important not only for the donor but this practice will also avoid undesirable transmission of disease to the recipient.

Screening of Donor:

Screening of the donor is done in order to ensure the quality of blood drawn and also to make sure that the loss of blood will not be harmful for the donor. Precautions are necessary to prevent the transfer of infectious agents through the blood used in transfusion therapy. The following are some of the criteria universally accepted for donor selection:

(1) Age: 18 to 60 years
(2) Haemoglobin: No less than 12.5 g/dL
(3) Haemotocrit: Male--no less than 41%;
Female--no less than 38%
(4) Pulse: Between 50 to 100/Min with no irregularities.
(5) Blood Pressure:
Systolic-- Between 90-180 mm Hg
Diastolic-- between 50-100 mm Hg
(6) Temperature: Normal (oral temperature not exceeding 37.5 degree C)
(7) Interval between donations: Minimum 16 weeks
(8) Weight of donor: For full; 1 unit(450 mL)
Weight of donor should be more than 49.5 Kg; for lower weight, take less amount of blood and use smaller quantities of anticoagulant.
(9) Absence of any chronic disease.
(10) Not pregnant in last six weeks
(11) Currently not taking any therapeutic measures.

Criteria for Rejecting Donors:

The donor is rejected if the person has:

(1) received dental surgery within 72 hours
(2) received transfusion within preceding 6 months
(possible source of hepatitis)
(3) received immunization against smallpox, mumps,
rabies or other within 2 weeks and against rubella
within two months)
(4) a history of malaria (for red cell products only)
for last 3 years.
(5) a history of jaundice (viral hepatitis) or AIDS
(acquired immuno deficiency syndrome)"

(iii) Measures, steps and safeguards which are required to be taken for the collection of Whole Human Blood are enumerated in detail and how donors should be screened and when they should be rejected are also prescribed. It is not known nor is it asserted anywhere in the petition or affidavit-in-rejoinder that the petitioner-pathologists or their Association observed any of the aforesaid safeguards or keep up-to-date record by maintaining registration of donor and various details of such donor. Even safety measures are required to be taken for transportation of blood after collection, storage of blood etc and it is not the case of the petitioners that they follow the very procedure or all safety measures which are required to be followed by a Blood Bank while tapping, collecting, cross-checking , storing, transporting blood of the donor. In chapter 17 of the very book significance of quality control in Blood Bank is stressed by the authors by making following observations:

"No other department in a pathological laboratory carries the same degree of responsibility as the blood bank, for in no other department is an error so likely to result in the death of a patient. Hence, the technician working in the blood bank must take appropriate quality control measures in order to avoid crucial errors.A reliable specimen, standard technique, properly functioning equipment, clean glassware, dependable reagents and their proper storage, and accurate recording, are all essential parts of the quality control system. Whenever, possible include a positive control to demonstrate that the reagent is potent.

Proper functioning of the blood bank can only be accompanied when the hospital staff realize the significance of accurate

specimen collection, proper identification of the specimen, appropriate handling of blood during transit, and transfusion of compatible blood to the correct recipient. Work must be organised in such a way that clerical, serological, or other errors, will be detected before any harm is done.

All crucial steps related to transfusion therapy and double checking by two separate individual. In the ward, any blood specimen taken from a patient should be put into a container that has been previously labelled with the patient's full name, the name of hospital, hospital number, ward number, and the date. Similarly, when a bottle of blood is received from the blood bank for transfusion, two people should check that the blood is administered to the right person.

Within the laboratory, double checking of blood grouping can be done by two technicians and results compared. For example, in the ABO grouping test, one should do the forward grouping and the other should perform the reverse grouping. In Rh-grouping, two antisers must be used and the results must tally. In case of compatibility testing, two workers should take different phases of compatibility testing--saline and albumin; thermophase and antihuman globulin. Both the workers should read their results independently and record their findings. The results should be compared at the end. In case of any discrepancy, both sets of tests must be repeated".

(iv) From the aforesaid observations and precautions and safeguards to be observed while tapping, collecting, matching, preserving, storing, transporting etc of Human Blood for the purpose of transfusion to the recipient, it must be observed that every step in the entire procedure is a very essential life saving step. At each and every stage starting from examining the donor of the blood, tapping, collecting, storing the blood in the bottle, transporting the blood and mixing of anticoagulant etc a large number of precautionary measures are required to be taken and every stage of entire procedure is so essential and is required

to be so scrupulously followed and that breach thereof may result into danger to the life of the recipient as well as to the spread of various diseases referable to transfusion of substandard blood. When the pathologists or pathological laboratories are carrying on these very activities and/or supplying the blood after collecting the to relatives of the donor of the blood for being transfused to the recipients whom they have never seen, their activity does not seize to be an activity of manufacturing or processing Whole Human Blood and some checks, controls and regulations of their activity are absolutely necessary.

(v) In the recent Interdisciplinary International Conference on AIDS-Law & Humanity conducted by the Indian Law Institute at New Delhi it is found by almost all the participants that generally HIV is transmitted in three major ways, one of them being through transfusion of blood.

31. Blood is an essential component of body which provides sustenance to life. There can be no greater service to the humanity than to offer one's blood to save the life of other fellow human-beings. At the same time, blood, instead of saving life, can also lead to death of the person to whom the blood is given if the blood is contaminated. As a result of developments in medical science, it is possible to preserve and store blood after it has been collected so that it can be available in case of need. There are blood banks which undertake the task of collecting, testing and storing the whole blood and its components and make the same available when needed. In view of dangers inherent in supply of contaminated blood, it must be ensured that the blood that is available with the blood banks for use is healthy and free from infection. At the same time, it shall have to be kept in mind the story of blood donors straight away going to pathologist or pathological laboratory for donating their blood for being given to the relative is not worth of acceptance. In fact, the notices issued to the petitioners clearly state that there is primafacie case with them to hold that the petitioners are selling blood after obtaining the same from professional blood donors. It is now found that no medical check up is done on the blood sellers, their health status is not examined. The blood trade flourishes with poor people like unemployed, rickshaw pullers, drug addicts selling the blood. Such blood sellers suffer from various infections and their haemoglobin is lower than the prescribed level. It has been reported that there are many persons who donate blood 5 to 6 times in a month; poverty makes them to do so at first but later it is reported to become like an addiction, the blood seller enjoying the dizziness due to reduced supply. In some places, strong

middle men operate for the blood banks by arranging for donors. The middle men dictate the charges to be paid and take a heavy commission; the selection of donors disregards the level of health etc. A large part of the professional donors are alcoholics or drug abusers, have indiscriminate sexual habits and are a high risk group for Hepatitis 8 and AIDS and are unfit to donate blood.

32. In the light of the aforesaid actual fact situation prevalent, it is unsafe to rely upon the tall claim of the petitioners that they are rendering professional services for which they charge professional fee and that they can not therefore be subjected to regular licensing process.

33 Lastly, Mr. K.C. Shah, Ld. AGP has relied upon various decisions of the Supreme Court and High Courts as to how much statutes prescribing regulatory measures in the larger interest of public should be interpreted and what should be the approach of the court while interpreting such provisions which are enacted in the welfare of people at large.

34 While interpreting such provision of the Statute which came to be introduced with specific avowed object, the Courts of Law shall have to be more agile and true to the purpose sought to be achieved by the Statute. When by enacting a provision, one of the objects is to prevent the unfortunate spread of deadly diseases and that too an underdeveloped country like India where the largest portion of its population is uneducated and where there is no sufficient literacy it becomes a Constitutional command for a judge to make such construction of the provision as will suppress the mischief, and advance the remedy and to suppress all evasions for the continuance of mischief. As put it by Maxwell on "The Interpretation of Statutes", 12th Edition, to carry out effectually the object of a Statute, it must be so construed as to defeat all attempts to do, or avoid doing, in an indirect or circuitous manner that which it has prohibited or enjoined:quando aliquid prhibeteur, prohibeteur at omne per quod devenitur ad illud. The court not only of the mischief sought to be avoided by the provision of a Statute will not be astute to narrow the language of a Statute so as to allow persons within its purview to escape its net. Secondly, the Statute may be applied to the substance rather than the mere form of

transactions, thus defeating any shifts and contrivances which parties may have devised in the hope of thereby falling outside the provision of the Statute. When the court of Law finds an an attempt on the part of Pathologists to carry on their nefarious activities, they are, in the words of Wilmot C.J., "brush away the cobweb varnish, and shew the transactions in their true light"

35 In the case of CHIMANLAL JAGJIVANDAS SHETH vs STATE OF MAHARASHTRA reported in AIR 1963 SC 665 His Lordship Justice Subba Rao (as His Lordship then was) speaking for the Apex Court in the context of Drugs Act, 1940 observed "that the main object of the Act is to prevent sub-standards in drugs, presumably for maintaining high standards of medical treatment. That would certainly be defeated if the necessary concomitants of medical or surgical treatment were allowed to be diluted, the very same evil which the Act intends to eradicate would continue to subsist." In the context of criminal liability under the provisions of the said Act, the question was as to whether the definition of "drug" as given in Section 3(b) of the said Act is comprehensive enough to take in not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals. It was contended before the Court that absorbent cotton wool, roller bandages and gauze would not fall within the definition of "drug" as they are not "substances". Negativating the said contention the Court held that the appropriate meaning of the expression "substances" in section is "things". Hence, absorbent cotton wool, roller bandages and gauze are "substances" within the meaning of the said expression. These things are used for or in "treatment".

36 Once again, in the context of Drugs and Cosmetics Act, 1940, in the context of criminal liability, in the case of Sk.AMIR vs THE STATE OF MAHARASHTRA reported in AIR 1974 SC 469 Justice Y.V.Chandrachud (as His Lordship then was) speaking for the Apex Court considered the question as to whether keeping or carrying drug on one's person is included in the definition of "storing or stocking". The court found that "The plain meaning of the word 'stock' in these provisions is 'to keep' and the injunction of the law contained in those provisions means no more than this that no person shall 'keep' for sale a misbranded drug or a drug in respect of which a valid licence is not held. It is not necessary that the drug should be 'stored' in a place in order that it can be said to have been 'stocked' for sale. If anyone keeps or carries a drug on his person in contravention of the terms of the Act and it is proved that the drug is kept or carried for sale, the act must fall

within the mischief of the law under consideration. 'Keeping' for sale is of the essence of the matter, not the mode and the manner of keeping. To keep for sale is to stock for sale".

37 In the case of SWANTRAJ & ORS vs STATE OF MAHARASHTRA reported in AIR 1974 SC 517 the Apex Court dealing with the provisions of Drugs & Cosmetics Act was concerned with the question as to whether the storage on adhoc basis without licence was punishable. Submission of the Learned counsel for the accused that the licence should not be insisted on for every place of make-shift storage in a farflung area served by a wholesaler may look reasonable was negatived by the court as a sensitive defence of the sick. After referring to Maxwell on the Interpretation of Statutes-12th Edition and the observations referred to hereinabove, Justice V.R.Krishna Iyer referred to the mischief rule propounded in Heydon's case which resolved--

> "that for the sure and true interpretation of all statutes in general (be they penal or beneficial, restrictive or enlarging of the common law) four things are to be discerned and considered: (1st) What was the common law before the making of the Act (2nd) What was the mischief and defect for which the common law did not provide (3rd) What remedy the Parliament hath resolved and appointed to cure the disease of the Commonwealth, and (4th) The true reason of the remedy and then the office at the Judges is always to make such construction as shall suppress the mischief and advance the remedy and to suppress subtle inventions and evasions for continuance of the mischief and pro privato commodo, and to add force and life to the cure and remedy, according to the true intent of the makers of the Act, pro bono publico"

38 The court thereafter made pertinent observations in the given situation of that case which are quoted hereunder:

> "If any godown, depot or premises become the nidus of the spurious, time-expired or nonscientifically stored drugs, can they be allowed to escape the coils of the penal law on the plea that they are not to be sold there without great peril to patient? Then legal shelter for spurious drug

> rackets would be judicially ensured. And this colours construction. Stocked for sale there and then? or to be sold certainly but elsewhere later? are the two alternative following from the language of section 18(1)(c). The former permits abuse through loopholes, the later tightens up but loads the dealer with expenses and need for more licences. Since risk to life and health is avoided by the later interpretation, we hold that the storage, even though for short spells and on adhoc basis and without intent to sell at that place but as part of the sales business, comes within the scope of 'storage for sale' in section 18(c) and Rule 62. To loosen the law on its joints is to play with life and therefore anti-humanist."

39 It is thus clear that the interpretation which permits abuse through loopholes is to be avoided and one which tightens up the provision for prevention of deadly epidemics is to be encouraged. Since the risk to life and health is avoided by interpretation which would include even the activity of Pathologist of collecting and storing and supplying blood, part of the activity which would fall within the definition, and therefore, it would be just and proper for this court to prefer the interpretation of Second Schedule to the activities being carried on by the pathological laboratories in the State of Gujarat. To loosen the law on its joints is to play with life and health and therefore anti-humanist. The grim predictions of a rapidly expanding epidemic of Human Immuno Virus (HIV) infection appears to be coming true with reported cases of AIDS more than doubling during the past years. According to the National AIDS Control Organisation (NACO), a total 2,095 cases of full blown cases of AIDS have been reported as of October 31, 1995 as against 849 cases till September 30, 1994. It is thus clear that amongst HIV positive cases there are instances from a significant proportion of recipients of blood and products, more so when large number of blood donors (professionals) are contributing to the spread of such disease.

40. In view of the aforesaid weighty observations of the Apex Court, and more particularly, in view of the wider connotation given to the word "manufacture" by statutory rules amended, from time to time, and in view of the finding of this court that the word "manufacture" shall have to be broadly construed so as to include various

processes sought to be incorporated by amending the rules, from time to time, by subordinate legislation, and further in view of the fact that the activities being carried on by the petitioners and/or pathologists or pathological laboratories as described by them in the memo of the petition as well as in their affidavits-in-rejoinder, include various processes which are, in fact, being carried on by them and shall squarely fall within the processes which a manufacture of blood or whole human blood actually carry out. There is no manner of doubt, therefore, if wider meaning is given to the word "manufacture" in the light of the objective sought to be achieved and the statutory rules framed, from time to time, that the activities being carried on by the petitioners and/or members of the association are activities and/or processes which fall within the definition of the word "manufacture" and therefore they are required to apply for and obtain licence as prescribed by section 18(c) of the said Act. Having recorded this conclusion after careful consideration of the pleadings and submissions made at the Bar and various amendments made in the Rules, from time to time, this court holds that the activities being carried on by the petitioners as described by them in the memo of their petition as well as in their affidavits-in-rejoinder fall within the concept of processes being carried on by them some of which are included in the wider connotation of the word "manufacture" and therefore they were and/or are liable to hold, apply for and obtain the licence as required by section 18(c) of the said Act, and failing which they are liable to face consequences including the one of prosecution.

WHAT RELIEF:

41. The respondents themselves in their affidavits-in-reply taken up the stand and/or contended that the petition is premature and liable to be dismissed as such as it is filed against issuance of notices to show cause and the petitioners could have by filing their reply shown cause/explanation, but instead there of they have rushed to the court and obtained widest/broadest ad-interim relief which has thwarted the implementation of welfare and beneficial Central legislation to the disadvantage of large number of patients who might have suffered or might have become victims of various nefarious activities being carried on by the pathologists and/or pathological laboratories. Ordinarily, the aforesaid contention shall have to be accepted and the petition shall have to be rejected as premature, but unfortunately, the learned single judge (N.H.Bhatt,J) of this court while issuing rule nisi granted ad-interim relief in widest possible term so

as to restrain the respondents even from proceeding further with the notice and from launching prosecution or taking any action, whatsoever, including action of prosecution for noncompliance with the requirement of replying to show cause notices. The adverse, hazardous and prejudicial ad-interim stay order of such a widest amplitude and unlimited in point of time shall and must have been noticed by concerned authorities, but unfortunately, the State machinery which is impersonal and which is lacking in knowledge as to how the court of law should be moved in such a situation, further nonassisted by any legal expert in the field, only took objection of petition being premature. The grant of adverse and prejudicial ad-interim relief of such widest amplitude as was granted in this court by the learned single judge has violently shocked the conscience of the Apex Court in the case of ASST.COLLECTOR, CENTRAL EXCISE,CHANDAN NAGAR vs DUNLOP INDIA LTD reported in AIR 1985 SC 330. In the said case it is observed by the Apex Court through O.CHINNAPPA REDDY,J that the public authorities function properly and bonafide with due regard to the public interest, the court must be circumspect in granting interim orders of far reaching dimensions or orders causing administrative, inconvenience. The court observed that while granting ad-interim or interim relief, prudence, discretion and circumspection are called for. Unfortunately, the grant of widest ad-interim relief by the learned single judge in this case has not only thwarted the process of welfare and beneficial legislation but has permitted the pathologists and class of pathologists from carrying on their activities of selling Human Blood which is collected from donors without obtaining any licence, thereby leading to possibility of grave danger hazard to public health. In fact, the ad-interim reliefs of this nature are deprecated by the Apex Court since long, but the practice of granting such ad-interim reliefs which would prejudicially affect the implementation of welfare legislation is found to exist even today. However, in the present case, unfortunately, the State Government did not take any action to get the ad-interim relief vacated as impersonal bodies like State ordinarily found themselves bound by the order of injunction granted by the highest court of State and hoping against hopes they wait till the decision or judgment on the petition and unfortunately pathologists or association of pathologists have succeeded in the present case by brazenfacedly continuing their ruthless activity of collecting and selling blood without licence and making huge profits therefrom thereby violently frustrating and devastating the very objective which was to be achieved by beneficial and welfare piece of legislation. However, in view of the fact that the State has not taken any action and the ad-interim relief granted in favour of

petitioners has operated, the respondents now can not be permitted to submit that the petition is premature because they have not taken any objection against operation of ad-interim relief and have miserably surrendered to the ad-interim relief granted by the highest court of the State, mostly not knowing as to what could be the remedy in a situation like this and secondly feeling that no course of action is left open to them when the highest court of the State has stayed the very process of issuance of show cause notices. It is, therefore, unfortunate, that the present petition can not be dismissed as premature as the very grant of ad-interim relief of widest amplitude has resulted into success of petitioners in contending before this court that atleast now no action could be taken on the stale show cause notices or on the materials allegedly collected relied upon while issuing show cause notices as back as 1983. To the aforesaid extent, they are right in contending that the petition can not be now dismissed outright as premature, but, at the same time, after finding recorded by this court, there is no manner of doubt that the petition shall have to be dismissed with costs which is quantified at Rs.25,000/- and it is declared that the Blood or Whole Human Blood is a "drug" and that the activities being carried on by the petitioners and/or various pathologists fall within the meaning of "manufacture" and they are therefore liable to apply for licence under section 18(c) of the said Act, failing which they are also liable to face consequences as enacted by law. Petition, therefore, though must fail on all points, shall have to be accepted partially only to the extent that the show cause notices in question are concerned because they have become stale and outdated based on stale materials allegedly collected the State can not be now permitted to take any action and they are required to be quashed and set aside solely on the ground that the show cause notices have become stale on which no action could be taken now, and now by issuing fresh show cause notices and after taking into consideration the explanation/reply, if any, submitted by the petitioners or other similarly situated persons in view of the declaration on law made by this court it will be open to respondents to proceed immediately to take action in accordance with law.

42. In the result, petition partially succeeds to the extent of quashing and setting aside the impugned show cause notices, dated 8.7.1983. However, it substantially fails as it is declared by this court that the Blood or Whole Human Blood is a "drug" and that the activities being carried on by the pathologists as is described by them in the memo of petition fall within the widest connotation of the word "manufacture" as defined by Section 18(c) of the

said Act.

43. Before parting with this judgment, this court feels that it would be failing in its constitutional obligation if it also does not issue simultaneous directions to the respondents to be complied with immediately and they are as under:

Respondents shall publish in Gujarat Samachar and Sandesh (Gujarati dailies) as well as Times of India and Indian Express (English dailies) the directions and/or instructions to the following effect:

(i) It is declared by the Gujarat High Court that the pathologists without licence to be obtained under section 18(c) of Drugs & Cosmetics Act can not collect, tap, cross-examine, cross-match and supply, distribute or sell blood even to the relatives of the donor.

(ii) It is hazardous to the health and liable to cause number of diseases, such as, AIDS, Malaria etc to purchase the blood and utilize the same for treatment of patients by administering the same during medical treatment as medicine.

(iii) The pathologists and/or pathological laboratories undertaking such activity of collecting/taping blood from persons and supplying such blood are required to obtain licence and it is hazardous to get blood from such pathologists or pathological laboratories if he/they does not/do not possess necessary licence.

(iv) The pathologists and/or pathological laboratories undertaking the aforesaid activity of tapping, collecting, cross-checking, cross-matching, filling the bottles with blood and supplying the Human Blood are required to obtain licence under section 18(c) of Drugs & Cosmetics Act, and unless such licence is shown to exist, the patients, their relatives or persons suffering from various diseases should not accept the blood as it is hazardous to their own health or to the health of patients when it is to be supplied.

44. The aforesaid directions shall be published both in English as well as Gujarati language within a week from today and it will be open to respondents to proceed to take action consistent with the declaration of law made by this court.

45. In the result, petition substantially fails. It is declared that the blood or the Whole Human Blood is "drug" and the activities of tapping, collecting, cross-matching

and keeping in bottle the blood of relatives would amount to "manufacturing of blood or Whole Human Blood" However, the petition is partially allowed by quashing and setting aside the stale show cause notices based on which respondents want to take action.

46. In the result, petition partially succeeds to the aforesaid extent but it substantially fails in view of the declaration of law made by this court. Petitioners are directed to pay the costs of Rs.25,000/- to respondents within a week from today by depositing the same in the registry of this court. Rule is made absolute accordingly.
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